matter was not described in the specification in such a way to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention at the time the application was filed). Applicants respectfully assert that these rejections should be withdrawn for the following reasons.

Specifically regarding the enabling requirement of §112, paragraph 1, the Examiner asserts that, although enabling for solid surfaces that are made of liquid impervious materials such as polystyrene, silicon, and Teflon, the specification does not reasonably provide enablement to alternative solid surfaces such as treated wood, metal, or crystal. Therefore, the Examiner acknowledges that the specification is enabling for liquid impervious sheets made of polystyrene, silicon, and Teflon, but not for treated wood, metal, or crystal. The Examiner argues, alternatively, that treated wood, although solid by nature, is not necessarily liquid impervious.

Applicants respectfully assert that persons of ordinary skill in the art, given the nature of the invention, need not engage in undue experimentation to determine which solids are liquid impervious and which are not. The issue is undue experimentation, and not what materials exist that can be solid yet not liquid impervious. As noted in *In re Wands*, 858 F. 2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), "the key word is 'undue', not 'experimentation.'" The depiction of a cross-section of the substrate 12 in Figure 2, in which unbroken slanted lines are used, clearly indicates to those skilled in the art that a solid, liquid impervious material is disclosed in the invention. Without undue experimentation, solids which are not liquid impervious, such as treated wood, will easily be discovered by those skilled in the art, and therefore no one will use them. Accordingly, the claims do not cover these solids. Likewise, solids

such as metal or crystal will be readily realized by those skilled in the art to be liquid impervious, and therefore easily interchangeable with other liquid impervious materials.

Moreover, the support surface is a mechanical element of the invention, and is therefore classified as a "predictable factor". In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. *In re Fisher*, 427 F. 2d 833, 839, 166 USPQ 18, 24 (CCPA 1970); see also *In re Vickers*, 141 F. 2d 522, 526-27, 61 USPQ 122, 127 (CCPA 1944); *In re Cook*, 439 F. 2d 730, 734, 169 USPQ 298, 301 (CCPA 1971). Applicants have not disclosed every liquid impervious solid which will work, nor have they disclosed those that will not work. To require such a complete disclosure would apparently necessitate a patent application with "thousands of examples." *In re Angstadt*, 537 F. 2d 498, 502, 190 USPQ 214 (CCPA 1976). This has the effect of discouraging inventors from disclosing their inventions. *Id.*

As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the scope of the claims, then the enablement requirement of 35 U.S.C. § 112 is satisfied. *In re Fisher*, 427 F. 2d at 839. By focusing on possibilities that may not work and/or were not specifically disclosed, the Examiner attempts to limit Applicants to claims to embodiments which are expressly disclosed, and therefore attempts to deprive Applicants of claims which adequately protect them. It is impracticable and unreasonable to require Applicants to make predictable every conceivable solid that is

also liquid impervious. If Applicants are limited to claiming only polystyrene, silicon, and Teflon for the analyte binding areas, a potential infringer could easily avoid "literal" infringement by merely finding another analogous liquid impervious solid which could be used for analyte binding areas. Therefore, the Examiner threatens to limit Applicants to claims which practically invite appropriation of the invention while avoiding infringement.

Specifically regarding the written description requirement of §112, paragraph 1, the Examiner re-asserts prior rejections of record that the specification does not provide literal support for the recitation of "analyte binding areas comprise liquid impervious sheets" in claim 10. Applicants believe it is clear that polystyrene sheets are clearly conveyed to those skilled in the art to be liquid impervious merely by looking at the drawings. The depiction of a cross-section of the substrate 12 in Figure 2, in which unbroken slanted lines are used, clearly indicates to those skilled in the art that a solid, liquid impervious material is disclosed in the invention. The clarification of this understanding by the addition of the phrase "liquid impervious" is not new matter, but merely further expounds upon that which was originally disclosed at the time the application was filed.

Courts have noted that applicants can rely on drawings alone to satisfy the written description requirement. See *In re Reynolds*, 170 USPQ 94 (CCPA 1971). In *Reynolds*, the applicant relied merely on Figure 2 of his drawing. The court permitted this, stating:

> by disclosing in a patent application a device that inherently performs a function, operates according to a theory or has an advantage, the patent applicant necessarily discloses that function, theory or advantage even though he says nothing concerning it. The application may later be amended to recite the function, theory, or advantage without introducing prohibitive new matter.

Id. at 98 (citing *Technicon Instruments Corp. v. Coleman Instruments*, 255 F.Supp. 630 (N.D. IL 1966).

Since Figure 2 of the original specification clearly conveys the substance of Claim 10 to those skilled in the art, regardless of how it accomplishes it, the essential goal of the description requirement was realized. By disclosing in the application a device that inherently performs the function of being liquid impervious, Applicants necessarily disclosed such function even though they said nothing concerning it. One skilled in the art would clearly appreciate from reading the application and viewing Figure 2 that the structure so claimed is the same structure disclosed. Therefore, the application could later be amended to recite this function without introducing prohibited new matter, because one skilled in the art would appreciate from reading the application that a polystyrene sheet is liquid impervious. The structures so claimed are the same structures originally disclosed, and later amendments adding clarifying phrases merely further explained what had been initially disclosed.

For the above reasons, Applicants respectfully request the Examiner withdraw the rejection of Claims 1-5 and 10 under 35 USC §112.

Claim Rejections Under 35 USC §102

Claims 1-5 and 10 are rejected under 35 U.S.C. §102(e) as anticipated by Wohlstadter et al. (U.S. Pat. No. 6,066,448) ("Wohlstadter"). Specifically, the Examiner states that Wohlstadter discloses an electrochemical device comprising a cell adapted to hold a sample wherein the cell has a surface having a plurality of analyte binding areas each having a different analyte binding substrate, and that the cell includes a plurality of working electrodes each adjacent an analyte binding area separate from another binding area by a distance, i.e. binding domains spatially aligned and in proximity to a plurality of electrodes. Applicants respectfully respond that Wohlstadter does not anticipate the present invention, for the following reasons.

Initially, Applicants argue that Wohlstadter's use of the phrase "spatial alignment" in connection with the binding domains is merely to describe the location of electrodes in relation to their corresponding analyte binding domains (see column 3, lines 40-44, and column 9, lines 53-65); there is no teaching of a structural requirement for a working electrode, with its corresponding analyte binding area, to be separate from adjacent binding areas by a minimal distance. Further, the goal of the Wohlstadter device is to detect multiple analytes solely via electrochemiluminescence ("ECL"), wherein electrodes are used merely to excite the ECL label to emit a photon (see column 1, line 56 to column 2, line 12). Light detection is the only manner disclosed for determination of the presence of analyte binding (see column 10, lines 7-26); there is no teaching of the use of electrodes to quantitatively detect enzyme reaction product.

In contrast to Wohlstadter, the present invention claims the novel structural requirement for each working electrode to be "separated from the nearest

adjacent analyte binding area by a distance", *in addition to* placement of "...each working electrode adjacent to one analyte binding area..." (see claim 1). The goal of the present invention is to detect multiple analytes in a single sample by using analyte binding areas at distinct, separate locations, a quiescent solution, and a plurality of working electrodes located within proximity of those distinct, separate locations (see page 3, lines 6-10). The independent electrode for each binding area is spatially separated from adjacent binding areas so that a measurement can be taken before cross-interference occurs due to diffusion of product from adjacent analyte binding areas (see page 3, lines 14-17). An electrode measuring the presence of a certain analyte is separated from the binding area of differing analytes by a predetermined distance, which is estimated by using the Einstein equation. This distance is the minimum distance allowable between the electrode measuring one type of analyte and a second analyte binding site in order to prevent cross-interference (see page 5, lines 1-17 and page 12, lines 5-16). Unlike Wohlstadter, Applicants' device teaches Fickian diffusion in order to eliminate cross-interference between different analytes. The phrase "spatial alignment" in Wohlstadter in no way describes alignment of the distinct binding areas in relation to each other to prevent cross-interference, but rather describes the proximity of an electrode to a distinct binding area. One of skill in the art will appreciate that Applicants' device detects multiple analytes through a different inventive method than Wohlstadter.

Further, the electrodes in Applicants' device are placed in close proximity to the analyte binding areas in order to detect enzymatic reaction product, whereas the Wohlstadter device places the electrodes in close proximity to the binding areas merely

to induce ECL. Claim 1 has been amended to clarify this difference, by the addition of the phrase "...working electrodes adapted to quantitatively measure an enzyme reaction product..." Applicants believe that addition of this phrase to claim 1 is not new matter, since the specification as filed teaches the quantitative measurement of enzyme reaction product by working electrodes (see page 5, lines 1-9, and page 3, lines10-15). Indeed, quantitative measurement of enzyme reaction product by the working electrodes is one reason why an individual working electrode must be separated from an adjacent analyte binding area by a distance, so that "the reaction product from the enzyme ... will not diffuse in sufficient quantity to interfere with the first working electrode" (see page 5 lines 4-9). The Wohlstadter invention does not teach quantitative measurement of enzyme reaction product by working electrodes. Rather, the Wohlstadter electrodes are used merely to induce ECL.

Moreover, Applicants' assay device is not limited to ECL alone, as Wohlstadter's device is, but instead is applicable to any electrochemical technique which utilizes an electrode, including chronoamperometry, cyclic voltammetry, linear scan voltammetry, pulse voltammetry, and differential pulse voltammetry (see page 9, lines1-11). Regarding the size of electrodes possible for the assay, Wohlstadter's electrodes must be large enough to be recorded by a light detector means, preferably on the sub-centimeter size (see column 9, lines 3-15). In contrast, Applicants teach that the dimensions are in the "millimeter" scale in terms of the diameters of the electrodes, the width of the antibody immobilization strips and the distances between detection electrodes. Applicants' concept also extends to the "micrometer" scale for the above stated dimensions, and teaches that the concept is also extendable down into

the "nanometer" scale using recently developed methodologies for depositing conducting materials with dimensions in this regime (see page 16, lines 3-17).

In light of the foregoing, Applicants respectfully assert that the Wohlstadter device does not attempt to accomplish multiple analyte determination using a system comparable to Applicants'. Wohlstadter does not teach Applicants' novel structural requirement of a minimal distance of separation between a working electrode of one analyte binding area and adjacent analyte binding areas to prevent cross-interference, and also does not teach quantitative measurement of enzyme reaction product by the working electrodes, which has been amended into claim 1 without adding new matter. Therefore, one skilled in the art would clearly recognize that the present invention is accomplishing a totally different function with its structure relative to the device disclosed in Wohlstadter. For these reasons, Applicants respectfully request that Examiner withdraw the rejection of Claims 1-5 and 10 under 35 U.S.C. §102(e).

CONCLUSION

For the foregoing reasons, Applicants submit that claims 1-5 and 10 as currently amended are in a condition for allowance. Accordingly, reconsideration and allowance for claims 1-5 and 10 is respectfully requested. Applicants believe that no additional fee is due as a result of this response. If, however, any additional fee or surcharges are deemed due, please charge same or credit any overpayment to deposit account no. 23-3000.

The Examiner is invited to contact the undersigned attorney with any questions or remaining issues.

Respectfully submitted,

WOOD, HERRON & EVANS

By: _____

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claim 1 has been amended as follows:

1. (Thrice Amended) A simultaneous electrochemical assay device comprising a cell adapted to hold a sample, said cell having a surface having a plurality of analyte binding areas, each of said analyte binding areas having a different specific analyte binding substrate; and a plurality of working electrodes adapted to quantitatively measure enzymatic reaction product, [and] each working electrode adjacent to one analyte binding area and separated from the nearest adjacent analyte binding area by a distance wherein said device does not have means to mix a sample in said cell.